PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P62308WO00	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/GB2004/003677	International filing date *(day/month/year)* 27.08.2004	Priority date *(day/month/year)* 29.08.2003
International Patent Classification (IPC) or national classification and IPC B29D11/00		
Applicant VISAQ LIMITED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 6 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29.11.2004	20.09.2005
Name and mailing address of the International preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Roberts, P Telephone No. +31 70 340-2305

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/003677

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-20	as originally filed
Claims, Numbers	
1-21	received on 24.01.2005 with letter of 21.01.2005
Drawings, Sheets	
1/2, 2/2	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 17-21

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 17-21

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/003677

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-7
	No:	Claims	8-16
Inventive step (IS)	Yes:	Claims	1-7
	No:	Claims	8-16
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

The subject matter of claims 17-21 were not searched and so have not been examined. That they are dependent claims is irrelevant.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

D1: US-A-4 284 399 (NEWCOMB PAUL D ET AL) 18 August 1981 (1981-08-18)
D2: GB-A-2 191 144 (COOPERVISION OPTICS) 9 December 1987 (1987-12-09)
D3: US-A-5 143 660 (HAMILTON RONALD S ET AL) 1 September 1992 (1992-09-01)
D4: WO 93/04848 A (BAUSCH & LOMB) 18 March 1993 (1993-03-18)

1
Novelty

1.1
The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 8-16 are not new in the sense of Article 33(2) PCT.

First regarding the features in claim 8.The insertion means of claim 8 has no technical features, nor are any apparent from the description. Also the reservoir is a result achieved during use of the male and female moulds. The insertion means is indeterminate and the insertion may even be done by hand. Similarly the ram means is any means which can be used to apply a force to the mould assembly- that this is done from a second position and to form a reservoir are results and features of the use of the apparatus.

D1 clearly discloses an apparatus for moulding contact lenses. The term "by the method of claim 1" is irrelevant as an apparatus must be claimed by its own technical features and can be ignored for novelty and inventive step (see Item VIII below). Further D1 discloses male and female moulds (which in any case have been inserted to form a reservoir) (see figs. 1 and 2), an insertion means (see above) and a ram means (see the "weight" in col.

2 lines 26 to 31). The remaining features of the claim can be ignored (see Item VIII).

Similar arguments apply to D2,D3,D4.

1.2
Claims 1-7 meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-7 are new in the sense of Article 33(2) PCT.

D1 does not disclose:

-initiating curing whilst keeping the pathway open
-applying the external force to insert the male mould further into the female mould to close the cavity

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

2
Inventive Step

2.1
The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 8-16 does not involve an inventive step in the sense of Article 33(3) PCT.

As claim 8 is not novel it follows that it does not involve an inventive step.

Dependent claims 9-16 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step as they are not novel or are design alternatives which would be usual practice for a skilled man.

2.2

The subject-matter of claim 1 is new (Article 33(2) PCT) (see 1.2 above).

The problem to be solved by the present invention may be regarded as to provide a method which enables reduction of gas bubble imperfections in the final lens

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
the non disclosed steps (d) and (e) enable gas to escape during polymerisation hence reducing bubbles in the final product. This is not hinted or taught in the prior art.

Claims 2-7 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 to D4 are not mentioned in the description, nor are these documents identified therein.

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Independent claims 1 and 8 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

Re Item VIII.

For Articles 5 and 6 PCT
1
The insertion means is not defined in the application and the features of the male and female moulds enabling the formation of the reservoir are not in the claims.

2
The features in the apparatus claim 8

"by the method of claim 1"

and
" wherein in making each contact lens the apparatus operates by:

inserting the male mould into the female mould to a first position relative to the female mould, the male mould and the female mould being adapted to together define a moulding cavity and a reservoir for lens forming material when the male mould is inserted into the female mould;
lens-forming material in liquid state previously introduced into the female mould being in part enclosed in the moulding cavity defined by the male and female moulds and in part expelled from the moulding cavity to the reservoir during insertion of the male mould into the female mould;
initiating curing of the lens-forming material in the moulding cavity whilst the male mould is in the first relative position and thereby keeping open a pathway between
the moulding cavity arid the reservoir so as to allow lensforming materials to flow from the reservoir into the moulding cavity to compensate for shrinkage of the lens-forming material during curing
the ram means applying an external force on the assembly of moulds to Insert the male mould further into the female mould to a second position relative to the female mould in which the moulding cavity is sealed off from the reservoir; and
allowing the lens-forming material to complete transformation to a fixed, glassy solid state with the sealed moulding cavity "

relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT and may be ignored for novelty and inventive step.

CLAIMS:

1. A method of moulding a contact lens using a male mould and a female mould, the method comprising the steps of:

(a) introducing lens-forming material in a liquid state into the female mould;

(b) inserting the male mould into the female mould to a first relative position to form an assembly of the male and female moulds in which the moulds together define a moulding cavity and a reservoir for lens-forming material;

(c) during the insertion of the male mould to the first position thereof expelling part of the liquid state lens-forming material from the moulding cavity to the reservoir;

(d) initiating curing of the lens-forming material in the moulding cavity whilst keeping open a pathway between the moulding cavity and the reservoir so as to allow lens-forming material to flow from the reservoir into the moulding cavity to compensate for shrinkage of the lens-forming material during curing;

(e) applying an external force on the assembly of moulds to insert the male mould further into the female mould to a second position relative to the female mould in which the moulding cavity is closed and sealed off from the reservoir;

(f) allowing the lens-forming material to complete transformation to a final, glassy solid state within the sealed moulding cavity; and

(g) removing the formed contact lens from the assembly of male and female moulds after the lens-forming

material has reached the final glassy solid state thereof.

2. A method as claimed in claim 1 wherein:

the assembly of male and female moulds is heated to initiate curing of the lens-forming material.

3. A method as claimed in claim 1 or 2 wherein:

the male and female moulds are heated at least until the closing of the mould cavity and prior to the closing of the mould cavity the lens-forming material is kept at a temperature above the glass transition temperature of the lens-forming material;

the lens-forming material is cooled below the glass transition temperature in the closed moulding cavity; and

removing the formed contact lens from the mould cavity occurs after the lens-forming material has cooled below the glass transition temperature thereof.

4. A method as claimed in any one of claims 1 to 3 wherein a thickener is added to the lens-forming material to increase the viscosity of the lens-forming material.

5. A method as claimed in any one of claims 1 to 4 which include the steps of:

forming the male and female moulds by an injection moulding process and using each pair of injection moulded male and female moulds only once in the formation of a single contact lens.

6. A method as claimed in claim 5 wherein:

a plurality of pairs of male and female moulds are injection moulded;

the liquid state lens forming material is deposited in the plurality of female moulds;

the plurality of male moulds are inserted into the female moulds, each being inserted to a first position in a respective female mould, to form a plurality of assemblies of male and female moulds;

the plurality of male moulds are all simultaneously displaced from the first positions thereof to the second positions thereof.

7. A method as claimed in any one of the preceding claims wherein:

the assembly(ies) of moulds is/are placed in a curing oven;

timing means is used to time duration of residence of the moulds in the curing oven; and

after a first measured time period the external force is applied to each male mould to move each male mould from the first position thereof to the second position thereof.

8. Apparatus for moulding a contact lens by the method of claim 1 comprising:

a male mould;

a female mould;

insertion means for inserting the male mould into the female mould; and

ram means;

wherein in making each contact lens the apparatus operates by:

inserting the male mould into the female mould to a first position relative to the female mould, the male mould and the female mould being adapted to together define a moulding cavity and a reservoir for lens forming material when the male mould is inserted into the female mould;

lens-forming material in liquid state previously introduced into the female mould being in part enclosed in the moulding cavity defined by the male and female moulds and in part expelled from the moulding cavity to the reservoir during insertion of the male mould into the female mould;

initiating curing of the lens-forming material in the moulding cavity whilst the male mould is in the first relative position and thereby keeping open a pathway between the moulding cavity and the reservoir so as to allow lens-forming materials to flow from the reservoir into the moulding cavity to compensate for shrinkage of the lens-forming material during curing;

the ram means applying an external force on the assembly of moulds to insert the male mould further into the female mould to a second position relative to the female mould in which the moulding cavity is sealed off from the reservoir; and

allowing the lens-forming material to complete transformation to a fixed, glassy solid state with the sealed moulding cavity.

9. Apparatus as claimed in claim 8 wherein the male and female moulds are shaped to provide the closed moulding cavity with an edge region triangular in cross-section.

10. Apparatus as claimed in claim 8 or claim 9 wherein the female mould is provided with an annular lip.

11. Apparatus as defined in claim 10 wherein said annular lip lies in a plane extending radially of the moulding cavity.

12. Apparatus as claimed in claim 11 wherein said male mould is provided with a frusto-conical region adjacent a spherical central region of the mould and the frusto-conical region abuts the annular lip of the female mould when the male mould is in the second position thereof.

13. Apparatus as claimed in any one of claims 8 to 12 wherein the male mould has a cylindrical portion and the female mould has a matched cylindrical portion and the matched cylindrical portions co-operate to ensure the correct location of the male mould in the female mould.

14. Apparatus as claimed in any one of claims 8 to 13 wherein each of the male and female moulds is an injection moulded mould and the assembly of moulds is for formation of a single contact lens.

15. Apparatus as claimed in any one of claims 8 to 14 comprising a curing oven in which the assembly of male and female moulds is locatable.

16. Apparatus as claimed in claim 15 comprising timing means for timing duration of residence of the assembly of male and female moulds in the curing oven and triggering

means for actuating the application of external force by the ram means when a chosen duration of residence is reached.

17. Apparatus as claimed in claim 16 wherein the ram means comprises a mass retention means for holding a mass in an elevated position above the male mould, which retention means releases the mass when triggered by the triggering means, the mass then falling to apply the external force on the assembly of moulds.

18. Apparatus as claimed in claim 17 which further comprises a lifting mechanism for lifting the mass to the elevated position thereof.

19. Apparatus as claimed in any one of claims 15 to 18 wherein the base of the curing oven is provided with a plurality of rows of rollers, wherein at least one roller in one of said rows is displaced vertically upwardly of the rollers in the other row(s).

20. Apparatus as claimed in claim 19 wherein the rollers are roller-balls.

21. Apparatus as claimed in claim 19 or claim 20 comprising a tray for transporting the assembly of male and female moulds in the curing oven, the tray having a recess formed in the underside thereof for receiving at least a portion of each roller in said row of rollers displaced vertically upwardly of the other row(s) of rollers.